SEP 1 0 2001

Section 6

K012902

510(k) Summary
Poly Per-Q-Cath PICC Catheters

510(k) Summary of Safety and Effectiveness Information
21 CFR 807.92

1. Submitter Information:

Submitter Name:	Bard Access Systems, Inc. [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 4923
Fax Number:	(801) 595 5425
Contact Person:	Stephanie Erskine
Date of Preparation:	August 24, 2001

2. Device Name:

Device Name:	Poly Per-Q-Cath PICC (Peripherally Inserted Central Venous Catheter)
Trade Name:	Poly Per-Q-Cath PICC Catheter
Common/Usual Name:	Poly Per-Q-Cath PICC
Classification Name:	Long Term Intravascular Catheter (80LJS)

3. Predicate Device:

Device Name:	Poly Per-Q-Cath PICC (Peripherally Inserted Central Venous Catheter)
Trade Name:	Poly Per-Q-Cath PICC Catheter
Common/Usual Name:	Poly Per-Q-Cath PICC
Classification Name:	Long Term Intravascular Catheter (80LJS)
Premarket Notification:	K001901, cleared for marketing on September 19, 2000

4. Device Description

- The Poly Per-Q-Cath PICC Single and Dual Lumen Catheters are open-ended catheters extruded from polyurethane loaded with barium sulfate for radiopacity. All are 63 cm in length
- The proximal ends of the catheter tubing are expanded to serve as strain reliefs for their connection to junctions with integral suture wings
- Integral extension legs are attached to the proximal ends of all SL and DL junctions of PQC catheters. The extension legs serve as a conduit for fluids into and out of the catheters, and can be occluded with provided thumb clamps
- Catheter tubing is marked with depth indicators, with "0" indicated to serve as a reference for catheter insertion point
- Catheters are provided sterile with inserted hydrophilic stylets. They are packaged individually, or sold in procedural kits containing accessories that are provided to aid in their placement

5. Intended Use

The modified Poly Per-Q-Cath PICC catheters are intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.

This is the identical intended use for the predicate Poly Per-Q-Cath PICCs. Please note that references to Midlines are not included in this Premarket Notification. Therefore, the Intended Use does not reference Midlines.

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6. Summary of Technological Characteristics in relation to Predicate Device:

6.1 Does the new device have the same indication statement?

Yes. The reference to Midlines was removed as Midlines are not included in this Special 510(k) Premarket Notification.

6.2 Does the new device have the same technological characteristics, e.g. design, material, etc.?

The basic fundamental scientific technology of the catheters has not changed. The strain relief connection has been modified to enhance resistance to kinking; barium sulfate content has been increased to enhance visualization by radiographic imaging techniques.

6.3 Could the new characteristics affect safety or effectiveness?

Yes. The modified strain relief design and the increased barium sulfate content of the catheter could affect safety and effectiveness of the device.

6.4 Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new issues of safety and effectiveness.

6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Design validation was performed to meet the recommendations of the FDA guidance document, *Design Control Guidance for Medical Device Manufacturers*, dated March 11, 1997.

The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95, and relevant ISO 10555 Standards were used to determine the appropriate methods for evaluating the modified device's performance.

Biocompatibility requirements of ISO-10993, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*, and the FDA-Modified ISO 10993 Test Profile for externally communicating, blood-contacting, long-term devices, were met. No materials are used in the manufacture of the modified device that have not already been cleared for similar applications by Bard Access Systems.

6.6 Are performance data available to assess effects of new characteristics?

Yes. Verification and validation testing was performed according to protocols based on the above-referenced guidance document recommendations and standards, as well as in accordance with in-house protocols. The modified devices met the acceptance criteria for the tests performed.

6.7 Do performance data demonstrate equivalence?

Yes. Performance data demonstrated that the modified Poly Per-Q-Cath PICCs are substantially equivalent to the predicate devices and/ or met pre-determined acceptance criteria, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

7.0 Conclusion

The modified Poly Per-Q-Cath PICCs met predetermined performance acceptance criteria of testing performed and are substantially equivalent to the predicate.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2001

Ms. Stephanie A. Erskine
Director of Regulatory Affairs
C.R. Bard, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K012902
Trade/Device Name: Poly Per-Q-Cath Single Lumen PICC Catheter
Regulation Number: 880.5970
Regulation Name: Peripherally Inserted Central Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 28, 2001
Received: August 29, 2001

Dear Ms. Erskine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION(S) FOR USE STATEMENT*

The Poly Per-Q-Cath PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For blood therapy, it is recommended that a 4 French or larger catheter be used.

Signature of 510(k) Submitter: Stephanie A. Erskine

Printed Name of Submitter: Stephanie A. Erskine
Director, Regulatory Affairs

Date: 28 Aug. '01

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K012902

Division Sign-Off _____
Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012902

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